

Table 3c. Other Oral Agents

<p><b>Author Year; Country</b></p> <p><b>Score</b></p> <p><b>Research Design</b></p> <p><b>Total Sample Size</b></p>	<p><b>Methods</b></p>	<p><b>Results</b></p>
<p><a href="#">Cardenas et al.</a> 2014</p> <p>US and Canada RCT Level 1</p> <p>PEDro=6</p> <p>Study SCI-F301 N=213</p> <p>Study SCI-F302 N=204</p>	<p><b>Population:</b> Patients with incomplete chronic SCI from two identical double-blinded, placebo-controlled studies (SCI-F301 and SCI-F302), from 45 and 33 centres, respectively, in the US and Canada. Both patient populations were balanced at baseline rendering comparability of patient populations. SCI-F301: Placebo (n=98): Mean age: 40.1 yr; Gender: males=85, females=13. Fampridine-SR (n=114): Mean age: 41.6 yr, Gender: males=100, females=14. SCI-F301: Placebo (n=100): Mean age: 40.5 yr. Fampridine-SR (n=103): Mean age: 41.3 yr.</p> <p><b>Intervention.</b> Patients were randomly assigned to either fampridine-SR 25 mg or placebo, twice daily for 2 wk in addition to a 2 wk titration, 12 wk of stable dosing, 2 wk of downward titration and 2 wk of untreated follow-up. Within treatment groups, patients were further stratified by concomitant antispasmodic medication within the two treatment groups.</p> <p><b>Outcome Measures:</b> Ashworth Spasticity Scale (AS) scores for bilateral knee flexors and extensors, Subject Global Impression (SGI), Penn Spasm Frequency Scale (SFS), International Index of Erectile Function (IIEF), Bowel and Bladder assessments, Sexual function.</p>	<p>1. There were no significant between-treatment differences except for an improvement among men treated with fampridine-SR on two IIEF domains - erectile function (p=0.016) and orgasmic function (p=0.032) in SCI-F301.</p>

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<p><a href="#">Cardenas et al. 2007</a></p> <p>USA</p> <p>RCT</p> <p>Level 1</p> <p>PEDro=6</p> <p>N=91</p>	<p><b>Population:</b> 72 men (19 female) with SCI; Injury level: C4-T10, AIS C-D; Age: mean 38-42 yrs, range 19-67; Time since injury at least 1 yr.</p> <p><b>Treatment:</b> Fampridine-SR 25mg 2 times per day or fampridine-SR 40mg 2 times per day for 8 wks (2-wk dose titration, 4 wks at fixed target dose, 2-wk downward titration) or placebo.</p> <p><b>Outcome Measures:</b> International Index of Erectile Function (IIEF), adverse events.</p>	<ol style="list-style-type: none"> <li>1. IIEF: non-significantly improved scores for fampridine-SR 25mg and 40mg 2 times per day vs placebo.</li> <li>2. Erection frequency: significantly improved for fampridine-SR 25mg group vs placebo.</li> <li>3. Adverse events: fampridine-SR 40mg: increased incidence of abdominal pain, dizziness, insomnia, paresthesia, nervousness, and anxiety vs placebo; fampridine-SR 25mg: increased incidence of pain vs placebo.</li> </ol>
<p><a href="#">Potter et al. 1998</a></p> <p>USA</p> <p>RCT</p> <p>Level 1</p> <p>PEDro=7</p> <p>Initial N=29</p> <p>Final N=26</p>	<p><b>Population:</b> 26 men; Age: mean 40.6 yrs; Injury level: C4-T12, tetraplegia (n=19), paraplegia (n=10), incomplete.</p> <p><b>Treatment:</b> Fampridine-SR or placebo 12.5mg for first week, 17.5 mg for 7 days, 1 week washout before cross-over.</p> <p><b>Outcome Measures:</b> Safety and efficacy of oral Fampridine-SR, patient satisfaction, quality of life, sensory and motor scores, Ashworth.</p>	<ol style="list-style-type: none"> <li>1. No significant results related to sexual function.</li> <li>2. 5 fampridine-SR patients reported erection improvement; however, 4 placebo patients also reported erection improvement.</li> </ol>